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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,532	03/20/2001	David Allen Schul	8003	2563

27752 7590 02/04/2004

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,532

Applicant(s)

SCHUL ET AL.

Examiner

Shaojia A Jiang

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003 and 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-63 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-63 and 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 28, 2003 and October 24, 2003 wherein claims 57-63 and 65-67 have been amended, claim 64 is cancelled, and claim 69 is newly submitted.

Currently, claims 57-63 and 65-69 are pending in this application.

Claims 57-63 and 65-69 are examined on the merits herein.

Applicant's amendment changing the limitation to "more than 10%" in the base claim 57 filed on November 28, 2003 with respect to the rejection of claim 57 made under 35 U.S.C. 102(b) as being anticipated by Erickson (3,751,569) for reasons of record stated in the Office Action dated April 23, 2003 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on November 28, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 57-63 and 65-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted November 28, 2003 with respect to amended claim 57 the base claim has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "more than 10% of a sterol fatty ester composition" because the recitation, "more than 10%" without an upper limit reads on 11%-100% of a sterol fatty ester composition. The original specification merely discloses "sterol esters are present at a concentration of from about 5% to about 30%, preferably from about 10% to about 20%. Vegetable Oils containing desired sterol fatty acid esters can be obtained by dissolving 5-30% sterol fatty acid ester, preferably 10-20% sterol fatty acid ester of the composition of this invention in the vegetable oil of choice for the final product." (see page 14 of the specification).

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson (3,751,569, of record) and Miettinen et al. (5,502,045, of record) and Wester et al. (WO 99/56558, of record).

Erickson discloses a clear cooking and salad oil comprising 0.5-10% by weight of the composition of a sterol fatty acid ester, which comprises 100% the particular monounsaturated fatty acid moiety, oleic acid moiety (oleic acid is a known monounsaturated fatty acid, see its chemical structure provided in the Merck Index page 6967). The sterol fatty acid ester employed in the composition therein is β -sitosteryl oleate or stigmasteryl oleate (see particularly Table I at col. 3-4 and Table II at col.5). See also col.1 lines 14-18 and 59-65; col.3 lines 1-30. Thus, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about 100% oleic acid moiety, which reads on more than 50% monounsaturated fatty acid moiety recited in the claim 57.

Miettinen et al. disclose that sterol fatty acid esters such as fatty acid esters of β -sitosterol and β -sitostanol are useful in compositions for reducing serum cholesterol level. See abstract, col.1 lines 10-15, col.3 lines 45-50, col.4 lines 19-24 and 64-65. The sterol fatty acid ester compositions therein can be added to oils (see particularly in

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Example 2-4 at col.5-6), such as at 3, 6, and 13 % by weight to rapeseed oil (Example 2-3 at col.5-6), and at about 10-20% weight to margarine (see Example 2-5 at col.5-6), and especially the rapeseed oil with the ester mixture added remained clear at room temperature (known at about 60-70⁰F) (see col.6 lines 23-25). Miettinen et al. also disclose that the sterol fatty acid esters therein employed in the compositions are prepared by, for example, β -sitostanol and rapeseed oil fatty acid methyl ester (i.e., interesterifying rapeseed oil fatty acid methyl ester with β -sitostanol to make β -sitostanol rapeseed oil fatty acid esters, see particularly at Example 1 at col.5 lines 34-47). The conversion rate of esterification therein was achieved to 98% (see col.5 lines 45-46). Thus, one of ordinary skill in the art would clearly recognize that the unesterified sterol level therein could be 2%, within the instant claim, less than 3, 5, or 10%.

Wester et al. discloses that fatty acid esters of phytosterols and phytostanols (such as sitosterol, campesterol and stigmasterol) are known to be useful in compositions for reducing serum cholesterol level. See abstract, page 1-3. Wester et al. also disclose that these sterol fatty acid esters compositions can be added to cooking oils and salad oils for the same purpose to reduce serum cholesterol level. See page 4 lines 9-31. Wester et al. also disclose that rapeseed oil employed for making sterol fatty acid esters is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (mainly monounsaturated) (see particularly at page 5 lines 14-17). Wester et al. further disclose that particular sterol fatty acid esters compositions comprise less than 5 or 7% saturated fatty acids (SFAs) (see particularly page 5 lines 8-

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9, and claims 1-2) and more than 50% PUFA as fatty acid moieties (see particularly page 5 lines 6-7 and claims 1-7).

Erickson does not expressly disclose a clear cooking and salad oil comprising more than 10% by weight of the composition of a sterol fatty acid ester. Miettinen et al. and Wester et al. do not expressly disclose particular sterol fatty acid esters compositions herein comprising more than 50%, about 55-80%, or about 60-70% of fatty acid moieties which are monounsaturated fatty acids (MUFAs) and less 50% polyunsaturated fatty acids (PUFA) moieties.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 10% by weight of the composition of a sterol fatty acid ester, and to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 10% by weight of the composition of a sterol fatty acid ester since more than 10% by weight of the composition of a sterol fatty acid ester to be added in food products such as vegetable oils has been disclosed by Miettinen et al. One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein since the sterol rapeseed oil fatty acid esters compositions at about 10% by weight are known to be added into the edible

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oil according to Miettinen et al. Moreover, rapeseed oil is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (including monounsaturated fatty acids and polyunsaturated fatty acids) but mainly monounsaturated fatty acids according to Wester et al. Further, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about 100% oleic acid moiety is known according to Erickson.

Thus, one of ordinary skill in the art would have reasonably interpreted that mainly monounsaturated fatty acids in a high content of unsaturated fatty acids, might be more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids in rapeseed oil. Hence, based on the teachings of Wester et al., the sterol rapeseed oil fatty acid esters compositions of Miettinen et al. would have reasonably been considered to comprise more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids.

Further, both Miettinen et al. and Wester et al. teach the same therapeutic usefulness of sterol fatty acid ester compositions for reducing serum cholesterol level and these sterol fatty acid esters compositions can be added to cooking oils and/or salads oils for the same therapeutic purpose. Therefore, one of ordinary skill in the art would have found it obvious to employ sterol rapeseed oil fatty acid esters compositions comprising more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid moieties and less than 50% PUFA moieties in an edible oil.

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Therefore, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Furthermore, the optimization of known amounts of active agents, e.g., monounsaturated fatty acids, polyunsaturated fatty acids, and saturated fatty acids in a known composition to achieve desirable physical properties is considered well within the skill of artisan, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on October 24, 2003 with respect to the rejection of claims 57-68 made under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (5,502,045) and Wester et al. (WO 99/56558) for reasons of record stated in the Office Action dated April 23, 2003 have been fully considered but are moot in view of the new ground(s) of rejection for the newly submitted claims set forth above.

Additionally, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

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found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as discussed above, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Applicant's working Examples of the specification at pages 23-32 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Examples provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art. Moreover, it is unclear that the compositions in Examples herein are within the instant claims, e.g., the particular percentage of MUFA and the particular percentage of a sterol fatty acid ester. Thus, the evidence in the examples does not clearly demonstrate being commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition. See MPEP § 716.02(d).

It is noted that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

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Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 29, 2004


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/2/04